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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,759	09/08/2003	David Lewis	48924-01030	1172

• 7590 04/19/2005

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,759

Applicant(s)

LEWIS ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the remarks filed on 12/21/04. Accordingly claims 1-23 remain pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-7, 11-14, 17-23 under 35 U.S.C. 103(a) as being unpatentable over Jager et al (5,955,058) in view of Lasserre et al (6,296,156) is maintained.

The rejection of claims 8-10 and 15-16 under 35 U.S.C. 103(a) as being unpatentable over Jager et al (5,955,058) in view of Lasserre et al (6,296,156) and further in view of Britto et al (6,149,892) is maintained.

Double Patenting

The provisional rejection of claims 1-16 under judicially created doctrine of obviousness-type double patenting over copending Applications 10/290,225 and 10/244,519 in view of Lasserre are maintained.

Response to Arguments

Applicant's arguments filed December 21, 2004 have been fully considered but they are not persuasive.

Applicant argues that inventors have found "that peroxides released from the rubber materials used as valve gasket or other compounds that can leach from the closure system into the formulation affect the chemical stability of certain active ingredients in solution formulations comprising a HFA propellant and a co-solvent". Applicant argues that the instability problem of such formulations has been solved by using "a canister with a rim with rounded edges which avoids contact of a sharp edge with rubber materials used as valve gaskets". Applicant believes that "no document of the cited references deals with the above-mentioned technical problem". This is not found persuasive because Jager et al discloses the stabilized solution formulations of the instant claims and Lasserre teaches the canister with rolled rim and rolled neck for storage and delivery of formulations comprising propellants. Lasserre discloses that the advantages of the said device include "it has no portion likely to be exposed to any corrosion by the product" (see col. 6, lines 36-46).

Applicant argues that Lasserre "is not at all concerned with the problem of stabilizing active ingredients in medicinal aerosol solution formulations". However applicants arguments are not persuasive because 1) the instant claims are mainly drawn to formulation products and method of making such products. The combined references provide all the limitations of the said claims, and it would have been obvious to one of ordinary skill in the art to have employed a suitable container for storage and

Art Unit: 1616

delivery of the said solution formulation. It is also noted that a newly disclosed property, use or function for known product is not support for patentability. The solution of Jager et al contained in the container of Lasserre et al would display stability. 2) Lasserre discloses that the product inside the container is not exposed to any corrosion, thus resolving the degradation problem. 3) Lasserre discloses that aerosols are currently being used for packaging and dispensing products in the fields such as dermatopharmaceuticals, which includes formulations comprising active agents such as steroids. Furthermore it discloses that "the invention provides a leaktight and reliable mounting of a valve on ANY kind of container. It is noted that preferred embodiments do not negate the broader teachings.

Applicant argues that "Britto deals with the technical problem of the adhesion of the drug present as a suspension in the formulation to the inner surfaces of the can", and "does not provide any hint to the claimed solution to the technical problem underlying the present invention". This argument is not persuasive. As mentioned above, the combination of the above references discloses a solution formulation in a container with rolled neck and rolled rim. Britto teaches that inner coatings of the canisters of the aerosols has been successfully done. One of ordinary skill in the art would have been motivated to take advantage of the said teachings and prepare aerosols in efficient containers. To meet the said limitations of the claims (under 35 USC (103), obviousness) Britto (used as a supporting art) does not need to state the

Art Unit: 1616

stability of the solutions, but to teach and disclose that which is missing from the primary reference(s).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found **either** in the references themselves or in **the knowledge generally available to one of ordinary skill in the art**. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it has been established that one of ordinary skill in the art would have been motivated to look in the art for a suitable container or device for storage and/or delivery of formulations.

With regard to the rejection of claims over the claims of the co-pending Application 10/290,225 (under double patenting), Applicant argues that "the rejection fails to compare any of the other features recited in the application" and that "the Office Action fails to provide proper basis for the provisional rejection". This is not persuasive. The co-pending Application recites claims drawn to a metered dose inhaler comprising an aerosol container equipped with a valve and containing a formulation comprising a solution of an active, a propellant, wherein the active is selected from budesonide, triamcinolone acetonide and rofleponide, and wherein the container is lined with an inert organic coating. The difference between the said claims and the instant claims in the specifications of the container such as rolled neck and rolled rim. Lasserre discloses

such container, and it would have been obvious to one of ordinary skill in the art to have employed the container of Lasserre for storage and/or delivery of the said solution.

With regards to the rejection of claims over the claims of the co-pending Application 10/244,519 (under double patenting), Applicant states that "the claims of the co-pending Application contain a different formulation than the formulation in the claims of present Application". This is not persuasive. Claims of the co-pending Application 10/244,519 are drawn to a pressurized metered dose inhaler comprising a container equipped with a metering valve and containing a solution comprising budesonide, a propellant and a co-solvent. The claims of the present Application are drawn to a formulation product comprising a solution of an active agent, a propellant, a co-solvent and optionally a low volatility component. Claim 10 recites that the active agent can be budsonide, triamcinolone acetonide, etc.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1616

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

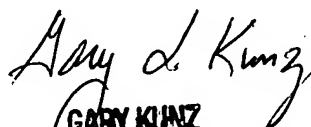
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
April 11, 2005



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600